

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

MARGARET FRIEDMAN, Executor of the
ESTATE OF MARY L. FRIEDMAN,) Case No. 1:21-cv-02083
Plaintiff,)
v.)) Judge Sara Lioi
MONTEFIORE *et al.*,)
Defendants.)
)

**DEFENDANT ARIEL HYMAN'S MEMORANDUM IN OPPOSITION
TO PLAINTIFFS' MOTION FOR REMAND**

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INTRODUCTION

The PREP Act’s language easily satisfies the standard for complete preemption of particular causes of action.... Congress said the cause of action for willful misconduct is exclusive, so it is.

Estate of Maglioli v. Alliance HC Holdings LLC, 3d Cir. Nos. 20-2833, 20-2834, 2021 U.S. App. LEXIS 31526, at *24 (3rd Cir., Oct. 20, 2021).

* * *

The Public Readiness and Emergency Preparedness Act of 2005, 42 U.S.C. §§ 247d-6d, 247d-6e (the “PREP Act”), expressly provides an exclusive federal cause of action for a certain subset of claims covered thereby—*i.e.*, those involving allegations of willful misconduct. Plaintiff’s claims in this case are the quintessential example of such claims: Plaintiff alleges that Defendants engaged in willful misconduct by deliberately falsifying and improperly administering COVID-19 diagnostic tests to the Decedent and other residents at the Montefiore nursing facility. The Third Circuit Court of Appeals—the only federal appellate court thus far to address this issue—has recently held that, because the PREP Act creates an exclusive federal cause of action for claims of willful misconduct covered by the Act, it completely preempts state law for purposes of those claims and justifies removal to federal court. *See Maglioli*, 2021 U.S. App. LEXIS 31526, at *19, *23-*24. When state law is completely preempted, federal question jurisdiction is properly invoked. *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 65 (1987).

In *Maglioli*, the Third Circuit observed that willful misconduct claims must be treated differently from ordinary negligence claims under the PREP Act for purposes of determining complete preemption. For ordinary negligence claims, the PREP Act provides immunity to defendants and a federal administrative remedy to compensate plaintiffs, but it does not create any federal cause of action. Because the PREP Act does not create an exclusive federal cause of action in connection with ordinary negligence claims, the Third Circuit and many other federal courts

have concluded that the PREP Act therefore does not completely preempt state-law negligence claims (though it does provide immunity that may be asserted in state court). By contrast, the PREP Act does provide an exclusive federal cause of action for claims of willful misconduct, which must be brought in the United States District Court for the District of Columbia. Because the PREP Act does create an exclusive federal cause of action for willful misconduct claims, the Third Circuit and other federal courts have expressly opined that willful-misconduct claims are completely preempted, and that Congress could not have been clearer on that point. The Third Circuit affirmed the remand in *Maglioli* because there was no allegation of willful misconduct.

In a recent decision from the Northern District of Ohio on motions to remand similar cases against Defendants, Judge Calabrese followed the Third Circuit's reasoning and confirmed that the PREP Act is indeed a complete preemption statute for purposes of willful misconduct claims relating to the use or administration of covered countermeasures. *Singer v. Montefiore et al.*, Case No. 1:21-cv-2102-JPC, ECF No. 20, p. 15 (N.D. Ohio Dec. 27, 2021). However, Judge Calabrese granted the plaintiff's remand motions solely on the grounds that Defendants purportedly did not establish that the COVID-19 tests referenced by the plaintiffs satisfied the statutory and regulatory criteria for "covered countermeasures." Defendants intend to appeal that ruling because it was evident from the face of the plaintiffs' complaints that the referenced COVID-19 tests did in fact qualify as "covered countermeasures." In any event, to resolve that issue for purposes of this case and to remove any possible doubt on the subject, Facility Defendants submitted with their memorandum a declaration from Richard Schwalberg, the Chief Operating Officer of Montefiore during the time in question (the "Declaration"), confirming that every COVID-19 test used at Montefiore during the relevant time period met the specified statutory and regulatory criteria to be considered "covered countermeasures." (See Dkt. 17-1).

Plaintiff wholly misses the crucial distinction between willful misconduct claims and ordinary negligence claims under the PREP Act by citing a host of factually inapposite authority. Not one of the cases cited or listed by Plaintiff involved willful misconduct claims covered by the PREP Act. Plaintiff also relies heavily on this Court’s decision in *Hudak v. Elmcroft of Sagamore Hills*, N.D. Ohio No. 5:21-CV-60. However, that case likewise did not involve direct allegations of willful misconduct in the use or administration of covered countermeasures as are present in this case. Furthermore, *Hudak* was decided before the Third Circuit’s decision in *Maglioli*. Though *Maglioli* is not binding on this Court, it is nevertheless the only federal appellate case to address the existence and scope of complete preemption under the PREP Act.

Plaintiff’s claims in this case are the prime example of the small subset of claims for which the PREP Act does completely preempt state law. Plaintiff expressly alleges willful misconduct in the use and/or administration of covered countermeasures (*i.e.*, COVID-19 diagnostic tests), and therefore the PREP Act provides the exclusive federal cause of action for those claims. As explained below, the mere fact that the PREP Act requires plaintiffs to exhaust an administrative remedy before filing suit does not defeat complete preemption, as is already well recognized in the context of ERISA. Furthermore, the fact that the U.S. District Court for the District of Columbia has exclusive subject-matter jurisdiction does not make removal to this Court improper—rather, it requires that this case instead be transferred to the D.C. District pursuant to 28 U.S.C. § 1631. For the reasons set forth below, Plaintiff’s asserted state-law claims are completely preempted, invoking a federal question and making removal to this Court proper. Plaintiff’s Motion for Remand should be denied.

THE PREP ACT

Congress enacted the PREP Act in the wake of the 2003 SARS outbreak to provide certain protections to health-care providers fighting on the front lines of future public health emergencies. The PREP Act provides immunity from liability for certain “covered persons” related to the manufacture, testing, development, distribution, administration, and use of medical countermeasures to diseases, threats, and conditions declared by the Secretary of Health and Human Services to constitute a public health emergency. Specifically, the Act provides that “a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration … has been issued with respect to such countermeasure.” 42 U.S.C. § 247d-6d. The immunity “applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.” *Id.* at § 247d-6d(a)(2)(B). Any state law that “is different from, or in conflict with, any requirement applicable [for immunity]” is expressly preempted. 42 U.S.C. § 247d-6d(b)(8).

For all claims barred by immunity under 42 U.S.C. § 247d-6d, the exclusive remedy for relief is established under § 247d-6e, which permits an individual to make a claim for benefits through the Countermeasures Injury Compensation Program, also known as the “Fund,” for a “covered injury directly caused by the administration or use of a covered countermeasure.” “The sole exception to the immunity from suit and liability of covered persons” is “for death or serious

physical injury proximately caused by willful misconduct....” 42 U.S.C. § 247d-6d(d)(1). In the case of willful misconduct, the exclusive remedy is a federal cause of action that must be “filed and maintained only in the United States District Court for the District of Columbia.” *Id.* § 247d-6d(e)(1).

On February 4, 2020, the Secretary of Health and Human Services issued a declaration under the PREP Act declaring COVID-19 to be a public health emergency (the “Declaration”). *See* 85 Fed. Reg. 15,198 (Mar. 10, 2020). The Declaration triggers the PREP Act’s immunity provisions, which extend through either (1) the final day the emergency Declaration is in effect, or (2) October 1, 2024, whichever occurs first. Covered countermeasures under this Declaration include “any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.” *Id.* at 15,202.

PLAINTIFF’S CLAIMS

Plaintiff is the Executor of the Estate of Mary L. Friedman (“Decedent”), a former resident at the Montefiore nursing facility. (Compl. ¶¶ 1-6). Plaintiff alleges that Defendants Montefiore, The Montefiore Foundation, The Montefiore Home, The Montefiore Housing Corporation, and The Menorah Park Foundation (collectively, the “Facility Defendants”) provided medical care and treatment to Decedent at the Montefiore nursing facility. (Compl. ¶¶ 2-6, 10-11). Plaintiff claims that Defendant Ariel Hyman was the Administrator at Montefiore. (Compl. ¶ 7).

Plaintiff claims that Decedent became ill and died as a result of COVID-19 in November 2020. (Compl. ¶ 18). Plaintiff also expressly alleges that Decedent’s contracting of COVID-19 and/or death was caused by Defendants’ willful misconduct. (Compl. ¶¶ 13, 16-17). Specifically,

Plaintiff alleges that Defendants willfully falsified and improperly administered COVID-19 diagnostic tests. (Compl. ¶¶ 16-17).

Plaintiff filed her Complaint in the Cuyahoga County, Ohio Court of Common Pleas, and the Defendant timely removed it to this Court. All Defendants have consented to the removal.

LAW AND ARGUMENT

A. Legal Standard for Remand.

“The federal courts are courts of limited jurisdiction.” *Robinson v. Michigan Consol. Gas Co.*, 918 F.2d 579, 582 (6th Cir.1990). Under 28 U.S.C. § 1441, a defendant may remove a civil action from state court to federal district court if “the district courts of the United States have original jurisdiction” over the case. *See Chicago v. Int’l Coll. of Surgeons*, 522 U.S. 156, 163 (1997) (“The propriety of removal thus depends on whether the case originally could have been filed in federal court.”). “If the district court determines that the removal was improper, the action must be remanded.” *Kent State Univ. Bd. of Trustees v. Lexington Ins. Co.*, 512 F.App’x 485, 488 (6th Cir.2013).

B. Plaintiff’s Claims Are Covered by the PREP Act.

A plaintiff’s claim for loss falls within the scope of the PREP Act if it was caused by “a covered person” and “aris[es] out of, relat[es] to, or result[s] from the administration to or the use by an individual of a covered countermeasure.” *See 42 U.S.C. § 247d-6d(a)(1)*. Here, it is evident on the face of Plaintiff’s Complaint that Defendants are “covered persons,” and that Plaintiff’s claims relate to the administration and use of “covered countermeasures”—specifically, COVID-19 diagnostic tests.

1. Defendants Are Covered Persons.

Plaintiff ostensibly does not dispute that Defendants are “covered persons” under the PREP Act, for she does not make any argument to the contrary. “Covered persons broadly include

individuals as well as private and public entities.” *Dupervil v. Alliance Health Operations, LLC*, 516 F. Supp. 3d 238, 248 (E.D.N.Y.2021). The term “person” is defined broadly and “includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.” 42 U.S.C. § 247d-6d(i)(5). A “covered person” under the Act includes:

(A) the United States; or (B) a person or entity that is (i) a manufacturer of [a covered] countermeasure; (ii) a distributor of such countermeasure; (iii) a program planner of such countermeasure; (iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or (v) an official, agent, or employee of a person or entity described in clauses (i), (ii), (iii), or (iv).

Id. § 247d-6d(i)(2). The term “program planner” means:

a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration [issued by the Secretary].

Id. § 247d-6d(i)(6). The Declaration defines “qualified persons” to include:

Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an emergency; (b) any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act; and (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.

Notice of Declaration, 85 Fed. Reg. 15198, 15201-15202 (March 17, 2020).

Federal courts have specifically found that nursing homes are “covered persons” under the PREP Act “to the extent [they] provide[] covered countermeasures to [their] residents.” *Rachal v. Natchitoches Nursing & Rehab. Ctr. LLC*, W.D.La., 2021 U.S. Dist. LEXIS 105847, at *11 (Apr.

30, 2021); *see also Garcia v. Welltower OpCo Group LLC*, C.D.Cal. No. SACV 20-02250JVS(KESx), 2021 U.S. Dist. LEXIS 25738, at *19 (Feb. 10, 2021). Moreover, the OGC has issued at least one opinion letter in response to a specific inquiry that concludes “senior living communities are ‘covered persons’ under the PREP Act when they provide a facility to administer or use a covered countermeasure in accordance with the Secretary’s March 10, 2020 Declaration under the PREP Act.” The letter specifically provides:

[A] senior living community meets the definition of a ‘program planner’ to the extent that it supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including by ‘provid[ing] a facility to administer or use a Covered Countermeasure in accordance with’ the Declaration.

Letter from Robert P. Charrow, General Counsel, HHS, to Thomas Baker, Foley Hoag LLP (Aug. 14, 2020).

Here, it is evident on the face of Plaintiff’s Complaint that Defendants are covered persons under the PREP Act, and Plaintiff does not make any argument to the contrary. Plaintiff alleges that the Facility Defendants operate a skilled nursing facility that has administered and used covered countermeasures in caring for its residents to prevent and treat COVID-19, including diagnostic tests. (Compl. ¶¶ 2-6, 13, 16-17). Plaintiff alleges that Defendant Hyman was an employee of the Facility Defendants. (Compl. ¶¶ 7). Therefore, Defendants are covered persons under the PREP Act.

2. Plaintiff’s Claims Relate to the Alleged Administration and Use of Covered Countermeasures. COVID-19 Tests are a COVID-19 Countermeasure.

Plaintiff's claims are covered by the PREP Act because, on their face, they relate to Defendants' administration and use of COVID-19 diagnostic tests, which are "covered countermeasures" pursuant to the Secretary's Declaration.¹

i. COVID-19 Diagnostic Tests Are Covered Countermeasures.

The PREP Act applies to "all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(1). The Act broadly defines the term "covered countermeasure" as:

- (A) a qualified pandemic or epidemic product;
- (B) a security countermeasure;
- (C) a drug, biological product, or device that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act; or
- (D) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health under part 84 of title 42, Code of Federal Regulations (or any successor regulations), and that the Secretary determines to be a priority for use during a public health emergency declared under section 247d of this title.

Id. § 247d-6d(i)(1). A "qualified pandemic or epidemic product" includes, *inter alia*, a device manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or to limit the harm such pandemic or epidemic might otherwise cause. *Id.* § 247d-6d(i)(7).

¹ In *Singer v. Montefiore et al.*, Case No. 1:21-cv-2102-JPC, ECF No. 20 (N.D. Ohio Dec. 27, 2021), Judge Calabrese recently granted motions to remand similar cases against Defendants on the grounds that the plaintiffs' claims in those cases purportedly did not relate to "covered countermeasures." Defendants are currently considering their right to appeal those cases. Yet in any event, it is abundantly clear in this case that Plaintiff's Complaint expressly relates to the alleged administration and use of COVID-19 diagnostic tests. Plaintiff's Complaint in this case mentions such tests over a dozen times. It is also abundantly clear that COVID-19 diagnostic tests are "covered countermeasures" under the Secretary's Declaration. Therefore, regardless of the ultimate outcome in *Singer*, the PREP Act unquestionably applies to Plaintiff's claims in this case.

As explained above, the PREP Act lies dormant until a declaration is issued by the Secretary of Health and Human Services in connection with a public-health emergency and identifying the specific “covered countermeasures” that will be recognized purposes of that particular public-health emergency. *See 42 U.S.C. § 247d-6d(a)(1).* For purposes of the COVID-19 public-health emergency, the Secretary’s Declaration specified that “covered countermeasures” include “any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.” 85 Fed. Reg. 15,202. The product must be either approved or cleared under the Federal Food, Drug, and Cosmetic Act (FDCA), an object of research exempt under the FDCA, or authorized for emergency use in accordance with the FDCA. 42 U.S.C. § 247d-6d(i)(7)(B). Therefore, pursuant to the plain language of the Secretary’s Declaration, COVID-19 diagnostic tests that are approved or authorized for emergency use by the FDA are “covered countermeasures” under the PREP Act.

ii. Plaintiff’s Claims Expressly Relate to the Alleged Use and Administration of COVID-19 Diagnostic Tests.

Plaintiff’s claims relate specifically to the alleged willful misconduct of Defendants in the use and administration of COVID-19 diagnostic tests. This is not a mere case of inaction, as in the District of Kansas cases relied upon by Plaintiff in her Motion to Remand. Plaintiff does not allege that Defendants failed to use or administer COVID-19 tests—rather, Plaintiff alleges that Defendants did use and administer COVID-19 tests and did so improperly. (Compl. ¶¶ 16-17). Plaintiff specifically alleges that Defendants willfully falsified and improperly administered COVID-19 diagnostic tests. (*Id.*) Though Plaintiff certainly also alleges other actions and inactions as contributing to Decedent’s injuries and death, the PREP Act’s coverage provisions do not

require that the use or administration of a covered countermeasure be the *exclusive* cause of injury or death. Rather, it merely requires that Plaintiff's claims for loss "relate to" the administration or use of a covered countermeasure. 42 U.S.C. § 247d-6d(a)(1). There can be no doubt on the face of Plaintiff's Complaint that her claims relate to the alleged falsification and improper administration of COVID-19 diagnostic tests.

Importantly, the PREP Act's immunity provisions *do not* require that the plaintiff's claim for loss relate to the administration to or use by *the plaintiff* of a covered countermeasure. Rather, they apply more broadly to *all* claims for loss relating to "the administration to or use by *an individual* of a covered countermeasure." *Id.* (emphasis added). In her Motion to Remand, Plaintiff inaccurately claims that the Declaration requires a covered countermeasure to be used by or administered to the plaintiff in order to trigger immunity. (Plaintiff's Motion to Remand at 8-9). Yet neither the Declaration nor anything in the PREP Act itself says anything of the sort. Both the Act and the Declaration expressly apply to all claims for loss relating to a covered countermeasure's administration to or use by an individual—not just the plaintiff. Moreover, courts reviewing this issue have made it clear that the PREP Act *does indeed apply* where there is "a close causal relationship to the administration of [a] covered countermeasure *to another individual*." See, e.g., *Sorace v. Orinda Care Ctr., LLC*, N.D.Cal. No. 21-cv-05714-EMC, 2021 U.S. Dist. LEXIS 217097, at *14 (Nov. 9, 2021); *Lollie v. Colonnades Health Care Ctr. Ltd.*, S.D.Tex. No. H-21-1812, 2021 U.S. Dist. LEXIS 172981, at *12 (Sep. 13, 2021) (emphasis added). The claims in Plaintiff's Complaint expressly relate to the alleged improper administration and use of COVID-19 diagnostic tests to individuals at the Montefiore nursing home, and therefore they are covered by the PREP Act.

iii. The COVID-19 Diagnostic Tests Allegedly Used and Administered by Defendants Were Authorized for Emergency Use by the FDA.

All the COVID-19 diagnostic tests allegedly used and administered at Montefiore were authorized for emergency use by the FDA, as required to be considered a “covered countermeasure.” Former Chief Operating Officer Richard Schwalberg, in the Declaration, confirms that every COVID-19 test used at Montefiore during the relevant time period was authorized for emergency use by the FDA and that Montefiore reasonably believed them to be so. Plaintiff has not contested this fact.

Moreover, even putting the Declaration aside, the fact that the referenced COVID-19 tests were FDA authorized is something that must be presumed from Plaintiff’s Complaint. Pursuant to the artful pleading doctrine, “a plaintiff may not defeat federal subject-matter jurisdiction by ‘artfully pleading’ his complaint” so as to omit requisite elements of a federal claim. *Sullivan v. Am. Airlines*, 424 F.3d 267, 271 (2d Cir. 2005). In such instances, a court will “read into a complaint elements that the plaintiff omitted.” *Id.* at 271-72. Courts must make “reasonable deductions, reasonable inferences, or other reasonable extrapolations” from the pleadings to determine whether it is facially apparent that a case is removable. *Roe v. Michelin N. Am., Inc.*, 613 F.3d 1058, 1061-1062 (11th Cir.2010). A removing defendant need only demonstrate the existence of a “discernable federal cause of action” on the face of a plaintiff’s complaint—not prove the veracity of every element of the plaintiff’s claims. *King v. Marriott Internatl., Inc.*, 337 F.3d 421, 425 (4th Cir.2003). “The law does not demand perfect knowledge or depend any less on reasonable inferences and deductions than we all do in everyday life.” *Pretka v. Kolter City Plaza II, Inc.*, 608 F.3d 744, 754 (11th Cir.2010).

It must logically be presumed that the COVID-19 tests Plaintiff contends Defendants falsified and failed to administer properly were FDA-approved or authorized because it is illegal

to market any COVID-19 test that is not FDA-approved or authorized. *See* 21 U.S.C. § 331. There is no reason to believe from the pleading that the COVID-19 tests referenced by Plaintiff are non-authorized tests, as the introduction of such tests into interstate commerce would be unlawful. It would make no sense for Plaintiff to claim that the decedent was harmed by Defendants' alleged falsification of COVID-19 tests *if those tests were not legal COVID-19 tests in the first place.*

It is also important to note that the PREP Act applies not just where the product in question actually meets the requirements of a “covered countermeasure,” but also where a defendant “reasonably could have believed that the product was a covered countermeasure.” *See Cannon v. Watermark Retirement Communities, Inc.*, E.D.Pa. No. 21-1451, 2021 U.S. Dist. LEXIS 133613, at *12 (July 19, 2021), fn. 4, citing U.S. Dep’t of Health & Human Services, Office of the Secretary, General Counsel, Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration Under the Act (April 17, 2021, as modified on May 19, 2020) at p. 4 (“[A] person or entity that otherwise meets the requirements for PREP Act immunity will not lose that immunity—even if the product is *not* a covered countermeasure—if that person or entity reasonably could have believed that the product was a covered countermeasure.”). Given that the Secretary’s Declaration defines “covered countermeasure” to include “any diagnostic” for COVID-19, and that it would be unlawful for manufacturers or vendors to market non-FDA-authorized COVID-19 tests, Defendants at the very least “reasonably could have believed” that the COVID-19 tests used in their facility were “covered countermeasures.”

In any event, Defendants have confirmed via the Declaration that the COVID-19 tests used and administered by Defendants at Montefiore were authorized for emergency use by the FDA

and therefore satisfy all the statutory and regulatory criteria to be considered “covered countermeasure” under the PREP Act.

C. Federal Question Jurisdiction Exists Because the PREP Act Completely Preempts Plaintiff’s State-Law Claims for Willful Misconduct.

1. The PREP Act Creates an Exclusive Federal Cause of Action for Plaintiff’s Willful-Misconduct Claims.

This Court has federal question jurisdiction over this case because the PREP Act completely preempts, displaces, and provides a substitute for Plaintiff’s state-law claims. This is true in this case because, unlike other cases in which federal courts have considered removal pursuant to the PREP Act, Plaintiff in this case has expressly alleged willful misconduct, and the PREP Act provides an exclusive federal cause of action and exclusive jurisdiction in the U.S. District Court for the District of Columbia for claims alleging willful misconduct. The Act provides, in relevant part:

(d) EXCEPTION TO IMMUNITY OF COVERED PERSONS

(1) IN GENERAL

Subject to subsection (f), the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person. For purposes of section 2679(b)(2)(B) of title 28, such a cause of action is not an action brought for violation of a statute of the United States under which an action against an individual is otherwise authorized.

(2) PERSONS WHO CAN SUE

An action under this subsection may be brought for wrongful death or serious physical injury by any person who suffers such injury or by any representative of such a person.

(e) PROCEDURES FOR SUIT

(1) EXCLUSIVE FEDERAL JURISDICTION

Any action under subsection (d) shall be filed and maintained only in the United States District Court for the District of Columbia.

42 U.S.C. § 247d-6d(d) – (e)(1) (emphasis added). The Third Circuit has recently confirmed that, while the PREP Act does not completely preempt state law for purposes of negligence claims—for which the PREP Act does not provide a federal cause of action—it does completely preempt state law for purposes of willful misconduct claims—for which it does provide an exclusive federal cause of action. *Maglioli*, 2021 U.S. App. LEXIS 31526 at *23-24. Because the PREP Act completely preempts state law for purposes of willful misconduct claims governed thereby, such claims therefore give rise to federal question jurisdiction and are removable to federal court. *Id.*

Generally, under the well-pleaded complaint rule, federal jurisdiction exists only when a federal question is presented on the face of a complaint. *Gully v. First National Bank*, 299 U.S. 109, 112-113 (1936). However, federal question jurisdiction may exist as a result of the “complete [or artful] preemption doctrine,” which applies where the preemptive force of a statute “converts an ordinary state common-law complaint into one stating a federal claim for purposes of the well-pleaded complaint rule.” *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 65 (1987). Under the “complete preemption” doctrine, claims pleaded under state law are removable to federal court where a federal statute has such “unusually powerful preemptive force” that the claims are deemed to arise under federal law. *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 7 (2003). Complete preemption is “really a jurisdictional rather than a preemption doctrine,” as it confers federal jurisdiction where Congress intended “to entirely replace any state-law claim.” *Franciscan Skemp Healthcare, Inc. v. Cent. States Joint Bd. Health & Welfare Trust Fund*, 538 F.3d 594, 596 (7th Cir. 2008).

“[T]o determine whether a federal statute completely preempts a state-law claim within its ambit, [courts] must ask whether the federal statute provides ‘the exclusive cause of action’ for the

asserted state-law claim.” *Sullivan v. Am. Airlines, Inc.*, 424 F.3d 267, 275-76 (2d Cir. 2005), quoting *Anderson*, 539 U.S. at 9. A federal statute that provides an exclusive cause of action for an asserted state-law claim “gives rise to original federal jurisdiction, and as a consequence allows removal under 28 U.S.C. § 1441,” with respect to the asserted state-law claim. *Sullivan* at 276. The Supreme Court has recognized the doctrine of complete preemption as a basis for federal question removal jurisdiction under 28 U.S.C. § 1441(a) in several different contexts. *See Avco Corp. v. Aero Lodge No. 735, Intern. Ass’n of Machinists and Aerospace Workers*, 390 U.S. 557, 559 (1968) (holding that the Labor Management Relations Act, 1947 completely preempted state court jurisdiction); *Metropolitan Life Insurance Co. v. Taylor*, 481 U.S. 58 (1987) and *Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004) (ERISA completely preempts state law); *Beneficial Nat'l Bank*, 539 U.S. at 7–11 (National Bank Act completely preempts); *See also In re WTC Disaster Site*, 414 F.3d 352, 375 (2nd Cir. 2005) (Air Transportation Safety and System Stability Act completely preempted state claims and ousted state courts of jurisdiction by creating an exclusive federal cause of action). “Once an area of state law has been completely pre-empted, any claim purportedly based on that pre-empted state-law claim is considered, from its inception, a federal claim, and therefore arises under federal law.” *Rivet v. Regions Bank of Louisiana*, 522 U.S. 470, 472 (1998).

The Third Circuit in *Maglioli* has been the only federal appellate court thus far to consider removal jurisdiction pursuant to the PREP Act, and it has confirmed that, while ordinary negligence claims covered by the PREP Act do not completely preempt state law and are not removable, willful misconduct claims covered by the PREP Act do completely preempt state law and are removable. Unlike Plaintiff in this case, the plaintiffs in *Maglioli* did not assert any claims

of willful misconduct—only claims of negligence. *Maglioli* at *19. In analyzing whether the PREP Act completely preempted the plaintiffs' claims, the court addressed two questions:

- (1) Does the PREP Act create an exclusive federal cause of action?
If it does,
- (2) do any of the [plaintiffs'] claims fall within the scope of that cause of action?

Id. In answering the first question, the court expressly held that “the PREP Act creates an exclusive cause of action for willful misconduct.” *Id.* The court explained:

The PREP Act’s language easily satisfies the standard for complete preemption of particular causes of action. It provides an “exclusive cause of action . . . and also set[s] forth procedures and remedies governing that cause of action.” Beneficial Nat'l Bank, 539 U.S. at 8. The [plaintiffs] admit as much. Where the PREP Act creates a cause of action, the [plaintiffs] say “that claim would be one for willful misconduct on the part of a covered person” that meets the statutory elements. Appellees' Br. 42. The Supreme Court has relied on the complete preemptive force of a statute to infer congressional intent to create an exclusive federal cause of action. Here, we have a better source of congressional intent: the words of Congress. Again, our analysis is straightforward. Congress said the cause of action for willful misconduct is exclusive, so it is.

Id. at *24 (emphasis added). Because the plaintiffs in *Maglioli* alleged only negligence and not willful misconduct, the court found in response to the second question that the plaintiffs' claims did not fall within the scope of the exclusive cause of action created by the PREP Act and thus were not completely preempted. *Id.* at *19, *25-*28. Nevertheless, the court unambiguously confirmed that the PREP Act does completely preempt willful misconduct claims that are covered thereby. *Id.* at *19, *23-*24.²

² At least one federal court determined that the PREP Act completely preempts all claims that it covers—even claims for negligence—though it is in the minority on this point. *Garcia v. Welltower OpCo Group LLC*, C.D.Cal. No. SACV 20-02250JVS(KESx), 2021 U.S. Dist. LEXIS 25738 (Feb. 10, 2021). Both the U.S. Department of Health and Human Services and the U.S. Department of Justice took that position as well. See HHS, Advisory Opinion 21-01 on the PREP Act (Jan. 8, 2021) (“HHS Advisory Opinion”); Fifth Amendment to Declaration Under the PREP Act, 86 Fed. Reg. 7872, 7874 (Feb. 2, 2021) (“[t]he plain language of the PREP Act makes clear that there is

None of the cases cited by Plaintiff involved allegations of willful misconduct related to the use or administration of covered countermeasures, for which the Third Circuit has now confirmed that the PREP Act provides an exclusive federal cause of action.³ Furthermore, like the Third Circuit in *Maglioli*, many district courts that have remanded negligence cases to state court have nevertheless expressly highlighted the distinction between willful misconduct claims and negligence claims under the PREP Act and suggested that willful misconduct claims are indeed completely preempted. *See Estate of Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518, 530 (D.N.J. 2020) (“Defendants cite 42 U.S.C. § 247d-6d(e)(1)—a subsection of the very PREP Act provision involved here—which provides that ‘[a]ny action under subsection (d) shall be filed and maintained only in the United States District Court for the District of Columbia.’ To me, that demonstrates only that Congress knew very well how to provide for an exclusive federal forum when it wanted to—i.e., for actions under subsection (d), which this is not.”); *Estate of Winfred Cowan v. Lp Columbia Ky*, W.D.Ky. No. 1:20-CV-00118-GNS, 2021 U.S. Dist. LEXIS 61708, at *14 (Mar. 30, 2021) (“Congress knows how to enact exclusive private rights of action when it chooses to do so.... Congress’ decision to provide an exclusive federal cause of action for willful misconduct under the PREP Act underscores its decision not to do so for the remaining claims.”); *Wright v. Encompass Health Rehab. Hosp. of Columbia, Inc.*, D.S.C. Civil Action No. 3:20-02636-MGL, 2021 U.S. Dist. LEXIS 59610, at *8 (Mar. 29, 2021) (“However, the PREP Act does provide for federal jurisdiction for specific causes of action alleging a nexus between willful misconduct and death or serious injury by stating such claims shall be filed and maintained only

complete preemption of state law as described above”); DOJ Statement of Interest, *Bolton v. Gallatin Ctr. for Rehab. & Healing*, LLC, No. 20-cv-00683 (M.D. Tenn. Jan. 19, 2021), ECF No. 35-1 (“DOJ Statement of Interest”).

³ In the small handful of cases in which the plaintiffs did include some kind of willful misconduct allegations, the courts nevertheless found that the plaintiffs’ claims were not covered by the PREP Act because they did not relate to the use or administration of covered countermeasures. Here, Plaintiff’s willful misconduct allegations directly relate to the use and administration of covered countermeasures—i.e., COVID-19 diagnostic tests.

in the District Court for the District of Columbia. See 42 U.S.C. § 247d-6d(d)-(e). Wright in this case does not make such allegations.”); *Shapnik v. Hebrew Home for the Aged at Riverdale*, S.D.N.Y. No. 20-cv-6774 (LJL), 2021 U.S. Dist. LEXIS 79447, at *32-33 (Apr. 26, 2021) (“The statute does create ‘an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct,’ and it provides a procedure for such suits.... [T]he federal cause of action created by the PREP Act can be brought only in federal court and only in the United States District Court for the District of Columbia, contrary to the usual rule that state courts have concurrent jurisdiction over federally-created causes of action.”); *Smith v. Colonial Care Ctr. Inc.*, C.D.Cal. No. 2:21-cv-00494-RGK-PD, 2021 U.S. Dist. LEXIS 53554, at *18 (Mar. 19, 2021) (“[A] state law claim may be completely preempted by the PREP Act if the claim (1) falls within the scope of the PREP Act’s immunity provision, and (2) is premised on allegations of death or serious physical injury proximately caused by willful misconduct by a person covered under the Act.”); *Maltbia v. Big Blue Healthcare*, D.Kan. No. 20-2607-DDC-KGG, 2021 U.S. Dist. LEXIS 60254, at *13 (Mar. 30, 2021) (“Here, the Petition alleges nothing about willful misconduct, so plaintiff’s claims cannot fall within the scope of the act’s first remedy.”); *Dupervil v. Alliance Health Operations, LLC*, 516 F. Supp. 3d 238, 253 (E.D.N.Y.2021) (“[O]nly claims involving ‘willful misconduct’ [are] able to be adjudicated in federal court.”); *Schuster v. Percheron Healthcare, Inc.*, 493 F. Supp. 3d 533, 539 (N.D.Tex.2021) (“[O]nly claims involving ‘willful misconduct’ [are] able to be adjudicated in federal court.”).

Here, Plaintiff expressly alleges willful misconduct in connection with Defendants’ administration and use of covered countermeasures. (Compl. ¶¶ 13, 16-17). Specifically, Plaintiff alleges that Defendants willfully falsified and improperly administered COVID-19 diagnostic tests. (Compl. ¶¶ 16-17). The PREP Act therefore provides an exclusive federal cause of action

for Plaintiff's claims. Because the PREP Act provides an exclusive cause of action—not just a federal administrative remedy—for Plaintiff's asserted state-law claims, it "gives rise to original federal jurisdiction, and as a consequence allows removal under 28 U.S.C. § 1441." *Sullivan*, 424 F.3d at 276.

2. Plaintiff's Complaint Need Only Raise One Federal Question to Justify Removal.

Plaintiff makes several unavailing arguments in an attempt to circumvent removal. First, Plaintiff relies on the fact that she has not pleaded only willful misconduct claims, but also negligence and/or recklessness claims. Yet removal pursuant to federal-question jurisdiction does not require that a plaintiff's complaint exclusively contain federal questions, but merely that it raise at least one federal question. "The presence of one federal question is enough to support removal of the entire action." *Prachun v. CBIZ Benefits & Ins. Servs.*, S.D.Ohio No. 2:14-cv-2251, 2015 U.S. Dist. LEXIS 12470, at *5 (Feb. 3, 2015). Because Plaintiff alleges willful misconduct related to the use and/or administration of covered countermeasures (*i.e.*, COVID-19 diagnostic tests), her Complaint contains at least one federal question under the PREP Act and is removable on that basis.

3. The PREP Act's Requirement that Plaintiffs First Make a Claim Against the Fund Before Filing Suit Does Not Defeat Complete Preemption.

Plaintiff also argues that the PREP Act does not actually give the federal courts original and exclusive jurisdiction over willful misconduct claims covered by the Act because plaintiffs must first make a claim against the recovery Fund before filing suit. As an initial matter, that argument is directly contradictory to the language of the statute, which expressly and unambiguously confers "**EXCLUSIVE FEDERAL JURISDICTION.**" 42 U.S.C. § 247d-6d(e)(1) (bold in original). Furthermore, the mere fact that there is a mandatory prerequisite to filing a cause of action (*i.e.*, the making of a claim against the Fund) does not mean that the federal courts do not

have original and exclusive jurisdiction over any such cause of action. Contrary to Plaintiff's suggestion, the PREP Act does not set up an administrative tribunal to adjudicate Plaintiff's claims. "The compensation fund is not a cause of action." *Maglioli* at *28. Rather, the PREP Act simply requires that a plaintiff must first make a claim against the Fund before filing his or her cause of action.

It is already well recognized in other areas that a mere requirement to exhaust an administrative remedy before filing suit does not defeat complete preemption. For example, plaintiffs are required to exhaust their administrative remedies before bringing a civil action under ERISA, and yet the Supreme Court has nevertheless confirmed that ERISA does provide the federal courts with exclusive original jurisdiction and does completely preempt state law. *Hitchcock v. Cumberland Univ. 403(b) DC Plan*, 851 F.3d 552, 560 (6th Cir.2017) (explaining that plaintiffs are required to exhaust administrative remedies); *Davila*, 542 U.S. at 221 (finding that ERISA completely preempts state law). In the case of the PREP Act, the Third Circuit has rightly observed: "Congress said the cause of action for willful misconduct is exclusive, so it is." *Maglioli*, 2021 U.S. App. LEXIS 31526, at *24.

Plaintiff misguidedly argues that "it would be 'logically inconsistent' to allow removal, because it would require the court to hold that it *does* have jurisdiction for removal purposes, but, at the same time, immediately find it lacks jurisdiction and must dismiss the action because the claim must be presented to an administrative body, not the court." (Plaintiff's Motion at 13). This is wrong for several reasons. First, as explained above, the PREP Act does not vest any administrative body with jurisdiction to hear and decide Plaintiff's claims. It simply requires that Plaintiff make a claim against the compensation Fund before filing suit. Second, there is no way to know on the face of the pleadings whether Plaintiff did, in fact, make a claim against the Fund

or not, and therefore it could not lead this action to be immediately dismissed. Any failure by Plaintiff to first make a claim against the Fund would need to be established by further fact finding. Moreover, even if it is eventually determined that Plaintiff failed to do so, it would simply mean that Plaintiff has not stated a viable claim for relief—not that the court lacks subject-matter jurisdiction.

D. Because the D.C. District Court Has Exclusive Subject-Matter Jurisdiction, This Case Must Be Transferred to the D.C. District Court—Not Remanded to State Court.

The fact that the PREP Act gives exclusive jurisdiction to the D.C. District Court does not make removal to this Court improper. The removal statute does not require that a removed civil action be one over which *the court to which it is removed* has original jurisdiction, but merely one over which “*the district courts of the United States*” have original jurisdiction. 28 U.S.C. § 1441(a). This is the Court to which Defendants were required to remove this case because it is “the district court of the United States for the district and division embracing the place where such action is pending.” 28 U.S.C. § 1441(a). However, the PREP Act provides that exclusive subject-matter jurisdiction shall be in the U.S. District Court for the District of Columbia. Accordingly, because another federal court is vested with jurisdiction, the proper remedy is to transfer the case to that court. 28 U.S.C. § 1631 mandates:

Whenever a civil action is filed in a court as defined in section 610 of this title or an appeal, including a petition for review of administrative action, is noticed for or filed with such a court and that court finds that there is a want of jurisdiction, the court *shall*, if it is in the interest of justice, transfer such action or appeal to any other such court (or, for cases within the jurisdiction of the United States Tax Court, to that court) in which the action or appeal could have been brought at the time it was filed or noticed, and the action or appeal shall proceed as if it had been filed in or noticed for the court to which it is transferred on the date upon which it was actually filed in or noticed for the court from which it is transferred.

(Emphasis added). In one of the cases cited by Plaintiff, the court noted that, because the transfer “statute’s language is mandatory,” the proper procedure for a removed case covered by the PREP Act and containing allegations of willful misconduct would be to transfer it to the District of D.C. *Smith*, 2021 U.S. Dist. LEXIS 53554 at *19-20; *see also Holman v. Sunrise Villa Culver City*, C.D.Cal. No. 2:21-cv-01054-RGK-JEM, 2021 U.S. Dist. LEXIS 74922, at *8-9 (Apr. 16, 2021). Therefore, the proper and mandatory course of action under federal law is to transfer this case to the District of D.C. pursuant to 28 U.S.C. § 1631—not to remand it to state court.

E. This Case Is Also Removable under the Federal-Officer-Removal Statute.

In addition to being removable pursuant to federal-question jurisdiction under the PREP Act, this case is also removable pursuant to the federal-officer-removal statute, 28 U.S.C. § 1442(a)(1). To remove a case under § 1442(a)(1), a defendant must meet three requirements: (1) the defendant must be a “person” within the meaning of the statute who acted under the United States or any agency or officer thereof, (2) the defendant must demonstrate that it performed the actions for which it is being sued under color of federal office, and (3) the defendant must show that it raised a colorable federal defense. *Bennett v. MIS Corp.*, 607 F.3d 1076, 1085 (6th Cir. 2010). Private parties may invoke federal-officer removal if they show they were “acting under” federal officers. *See Watson v. Philip Morris Cos.*, 551 U.S. 142, 147 (2007). Specifically, a private defendant must show that its actions “involve an effort to assist, or to help carry out, the duties or tasks of the federal superior.” *Id.* at 152. The phrase “acting under” is broad, and courts must construe it liberally. *Id.*

As alleged operators and employees of a nursing home participating in the Medicare and Medicaid programs, Defendants were “acting under” federal authority in responding to the COVID-19 pandemic. Nursing homes have a special relationship with the federal government in which they provide an essential service on the government’s behalf. This has been especially true

in the context of the COVID-19 public health emergency, as nursing homes essentially became extensions of CMS and relied upon constantly changing directives from CMS to prevent the spread of the disease. Nursing homes were not just providing private services to individuals, but providing a public health service on behalf of the federal government in seeking to prevent the spread of COVID-19 to those most vulnerable to it. As health-care providers on the front lines, nursing homes were tasked with providing a public service in combating COVID-19 that the federal government could not provide on its own. Because Defendants were operating pursuant to Medicare provider contracts with the federal government and at CMS's direction in responding to COVID-19, they are entitled to invoke federal-officer removal.

CONCLUSION

Plaintiff's Complaint in this case contains express claims of willful misconduct relating to the use and administration of COVID-19 diagnostic tests, and the PREP Act provides an exclusive federal cause of action—not just a federal administrative remedy—for those claims. *See Maglioli*. Because the PREP Act expressly creates an exclusive federal cause of action covering Plaintiff's asserted state-law claims, those state-law claims are completely preempted. Plaintiff's claims therefore arise under federal law, invoke the federal-question jurisdiction of the federal courts, and are removable to this Court. Plaintiff's Motion for Remand must be denied, and this case should instead be transferred to the U.S. District Court for the District of Columbia.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing document was filed with the Clerk of Courts using the ECF system on January 13, 2022, which will send notification of such filing to all attorneys of record.

/s/ Matthew D. Gurbach
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